

U.S. ENVIRONMENTAL PROTECTION AGENCY ADMINISTRATOR ANDREW WHEELER

MEMORANDUM FOR AWARENESS

Date of Submission: Thursday, July 9, 2020.

TOPICS FOR DISCUSSION

1. ISSUE/REQUEST: For Awareness, OCSPP is Preparing to Respond to the Court's Deadline of July 21, 2020 to Respond to the 2009 Natural Resources Defense Council (NRDC's) Petition to Cancel all Tetrachlorvinphos (TCVP) Pet Uses.

About TCVP

- In April 2009, the Natural Resources Defence Council (NRDC) petitioned the EPA to cancel all TCVP pet products alleging risks to toddlers from hand-to-mouth exposure from residential pet-care uses. TCVP is an organophosphate (OP) insecticide used to control fleas, ticks, various flies, lice, and insect larvae on livestock and domestic animals and their premises. TCVP is also applied as a perimeter treatment. There are no registered-crop uses for TCVP.
- Residential uses include pet collars, flea and tick powder, and pump sprays for pets. Residential risks stem from pet uses.
- There are limited alternative pet collars to replace TCVP collars.
- Most pet-use products are registered by Hartz Mountain Corporation. One dust product with pet uses is registered by Chem-Tech and will be amended to delete use on cats and dogs.
- TCVP is currently in registration review, with a full updated human health risk assessment anticipated in 2021, and the Proposed Interim Decision to follow.

TCVP Petition/Litigation

- In April 2009, the Natural Resources Defense Council (NRDC) petitioned the EPA to cancel all TCVP pet products alleging risks to toddlers from hand-to-mouth exposure from residential pet-care uses. In short, NRDC asserted that toddlers are at risk because they touch their pets, get TCVP on their hands, and then mouth their hands.
- Due to uncertainty around the physical form of TCVP present in the collars, the
 agency was unable to fully respond to NRDC's petition from 2009 to 2017. EPA
 sent NRDC a letter in 2017 stating that EPA intended to address any risk mitigate
 any risk mitigation as part of registration review.

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- The EPA completed an ecological risk assessment =was-completed-September 22, 2015, and ecological exposure from finding no ecological risks of concern from pet uses, pet uses is not expected to result in risks of concern.
- A revised human health risk assessment was issued in 2016.
- EPA continued negotiations with Hartz from 2017 to 2019 to determine how to confirm the physical form for TCVP in the pet collars.
- In May 2019, NRDC filed a mandamus petition with the Ninth Circuit Court of Appeals, alleging an "unreasonable delay" on EPA's part to respond to NRDC's petition to cancel all TCVP pet uses.
- Oral arguments were held in early February 2020 and the Court issued its decision on April 22, 2020 requiring EPA to respond to the petition within 90 days of the decision date (*i.e.*, by July 21, 2020) by either initiating cancellation or denying NRDC's petition to cancel pet uses.

Recommended Action

- EPA intends to deny the petition based on risk estimates for the liquid sprays and registrant-proposed mitigation for the dust powders and collars.
 - Risk estimates for liquid spray products do not exceed the agency's level of concern
 - <u>o</u> The mitigation involves Hartz The registrant is proposing to-voluntarily canceling the dust powders and —one pet collar, to amend certain collar registrations to restrict use by pet age/weight, and to redesign the remaining collars to reduce risk estimates.
- The specific terms and conditions of the registrantHartz' voluntary agreement is under development.
- EPA's OPP and OGC are working on the agency's formal-denial response will be which is supported by a revised pet-use risk assessment and an economic impact assessment.

BACKGROUND:

- TCVP is an organophosphate (OP) insecticide used to control fleas, ticks, various
 flies, lice, and insect larvae on livestock and domestic animals and their premises.
 TCVP is also applied as a perimeter treatment. There are no registered crop uses
 for TCVP.
- Residential uses include pet collars, flea and tick powder, and pump sprays for pets. Residential risks stem from pet uses.
- There are limited alternative pet collars to replace TCVP collars.

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- Most pet-use products are registered by Hartz Mountain Corporation. One dust product with pet uses is registered by Chem-Tech and will be amended to delete use on cats and dogs.
- TCVP is currently in registration review, with a full updated human health risk assessment anticipated in 2021, and the Proposed Interim Decision to follow.

Human Health and Ecological Conclusions

- The ecological risk assessment was completed September 22, 2015, and ecological
 exposure from pet uses is not expected to result in risks of concern.
- A revised human health risk assessment was issued in 2016. OCSPP intends to finalize a revised human health residential pet use assessment for pet uses only on or before July 21, 2020, which will include additional registrant data provided in August 2019.
- The 2020 revised human health residential pet use assessment is only presenting risk estimates with the 10x FQPA Safety Factor. There are some residential post-application risks of concern for certain pet collars and pet dust products.
 - Residential post-application risk estimates for pet collars are refined as
 possible using studies submitted in August 2019, including a submitted dust
 torsion study for the ratio of liquid/dust in the TCVP pet collar products and
 two chemical-specific transferable residue studies.
- Cancer risk estimates have also been estimated for TCVP with potential risks identified for residential post-application exposure.
- EPA will be holding a SAP meeting in September 2020 to receive external peer review on methods for establishing data-derived safety factors for each OP; although it is unclear if the safety factors for TCVP will be impacted by this SAP.

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Stakeholder Reaction and Communications

- Some press is possible due to ongoing litigation related to the NRDC petition to cancel TCVP use in pet products.
- No rollout is proposed. OCSPP/OPA will have a desk statement on-hand for any
 press inquiries. OPP is working on potential back-pocket questions and if a
 website update will be needed.

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